

### REMARKS

Claims 1-31 are pending. Claim 10 has been amended. Reexamination and reconsideration of the pending claims are respectfully requested.

#### Claim Rejections – 35 U.S.C. § 103

Claims 1-6, 8-17, 19-21, and 23-31 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,011,991 (“Mardirossian”) in view of U.S. Patent No. 6,230,048 (“Selvester”).

To establish a *prima facie* case of obviousness under Section 103, three basic criteria must be met. *M.P.E.P.* § 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant’s disclosure. *See M.P.E.P.* § 2143.1. Moreover, it is improper to combine references where the references teach away from their combination. *See M.P.E.P.* § 2145. The Examiner’s proposed combination of references does **not** meet the above criteria with respect to the subject matter of the claims.

With respect to independent Claim 1, Mardirossian does not teach or suggest, among other things, a method of providing real-time decision support in the review of physiological data including the act of interpreting the physiological data based on a predetermined set of criteria to generate an interpretation. In contrast, Mardirossian discloses a system that utilizes sensors 7 to detect event related potentials indicative of a “brainprint” or brain activity of an individual 3. Col. 6, lines 34-42. The “brainprint” is transmitted as wireless signals 13 via satellite 15 to a remote location. The signals 13 are processed at the remote location through equalizer 29, demodulator 31, parallel to serial converter 33, deinterleaver 35, decoder 37, descrambler 39, digital estimator 41, and computer 21. Col. 6, line 62-col. 7, line 2. The signals 13 can remain in digital form or can be transformed into analog form as illustrated in Fig. 3. Col. 7, lines 5-17. The computer 21 receives the signals 13 from an individual and can compare the received signals 13 to files or patterns of measured brain activity or responses previously obtained from the

individual to determine what the individual was attempting to communicate. Col. 7, line 24-col. 8, line 57.

The system of Mardirossian does not interpret the "brainprint" based on a predetermined set of criteria to generate an interpretation. The meaning of an individual's "brainprint" is not determined until after the "brainprint" is compared to preestablished patterns from the same individual.

The Examiner has indicated that Mardirossian discloses this element at col. 3, lines 46-47; col. 6, line 63-col. 7, line 15; and col. 5, line 58-col. 6, line 29. Office action dated May 6, 2004, page 3. During the interview, the Examiner explained and specifically pointed to col. 3, lines 44-47, which indicates

a data acquisition device receives the signals representative of the physiological activity generated in the monitored brain, and transforms the signals into a pattern or curve corresponding to the monitored brain activity

to indicate that Mardirossian discloses a method of providing real-time decision support in the review of physiological data including the act of interpreting the physiological data based on a predetermined set of criteria to generate an interpretation. The Examiner further explained that the system in Mardirossian is interpreting the physiological data by transforming the signals into a pattern or curve.

Applicant disagrees. Applicant respectfully submits that the terms "interpreting" and "interpretation" must be given their plain meaning. "Interpret" is defined as "to give or provide the meaning of; explain; explicate; elucidate; to construe or understand in a particular way; to bring out the meaning of by performance or execution; to perform or render according to one's own understanding or sensitivity; to translate orally; to transform (a program written in a high-level language) with an interpreter into a sequence of machine actions, one statement at a time, executing each statement immediately before going on to transform the next one; to read (the patterns of holes in punched cards) with an interpreter, printing the interpreted data on the same cards so that they can be read more conveniently by people." Webster's Encyclopedic Unabridged Dictionary of the English Language, 998 (1996).

The system in Mardirossian is simply sensing, with sensors 7, electrical signals produced by the brain and generating a waveform (as illustrated in Fig. 3 if analog form is preferred). The waveform is a visual representation of the raw data signals that were sensed by the sensors 7

over a period of time. The raw data signals are not interpreted to generate the waveform, but rather, the raw data signals make up and create the waveform. Furthermore, a predetermined set of criteria is not used to create the visual representation of the raw data because the waveform is a visual representation of the raw data illustrated over a period of time.

Mardirossian also does not teach or suggest, among other things, a method of providing real-time decision support in the review of physiological data including the act of displaying the interpretation and the correlated physiological data records on a display as acknowledged by the Examiner. Office action dated May 6, 2004, page 3.

Selvester does not cure the deficiencies of Mardirossian. Selvester does not teach or suggest, among other things, a method of providing real-time decision support in the review of physiological data including the act of displaying the interpretation and the correlated physiological data records on a display. In contrast, Selvester discloses a computer that processes ECG data to arrive at an interpretation output signal, which is capable of driving a pictorial output display structure. Col. 6, lines 40-47. Based on the interpretation output signal, a visual presentation of a pictorial view of the heart can be displayed on a display. Col. 9, lines 53-62; col. 19, line 57-col. 20, line 57. The visual presentation of the heart can include markers that represent one or more selected heart conditions based on the interpretation of the ECG data (see Fig. 6A). Id. The system of Selvester does not display the correlated physiological data records.

In addition, there is no suggestion or motivation to combine the teachings of Mardirossian and Selvester. First, Mardirossian discloses a system that acquires and analyzes brain signals to determine what an individual intended to communicate as opposed to Selvester, which discloses a system that acquires and analyzes cardiology data to assess heart related conditions. Second, there would not be a reason to provide a pictorial display of heart conditions (as in Selvester) in a system that only acquires brain signals (as in Mardirossian) and does not include a method of acquiring heart signals. Furthermore, the references teach away from being combined because of the vast differences between systems and algorithms used to analyze brain data and heart data. Very clearly, the same system and algorithm cannot be used to analyze both brain data and heart data, therefore, a person of ordinary skill in the art is not going to look for systems that analyze heart data when looking for ways to improve a system that analyzes brain data.

For at least the reasons noted above, Mardirossian and Selvester do not teach or suggest the subject matter of Claim 1. Accordingly, independent Claim 1 is allowable. Claims 2-9 depend from independent Claim 1, and are therefore allowable for at least the reasons set forth above with respect to Claim 1. In addition, the additional subject matter defined by dependent Claim 2 provides separate bases for allowance.

With respect to Claim 2, Mardirossian does not teach or suggest establishing a communications link to an expert location; transmitting information concerning the interpretation to the expert location; and displaying a communication from the expert location on the display. The Examiner indicates that these elements are disclosed at col. 2, lines 54-56 and col. 3, lines 47-49 of Mardirossian. Applicant disagrees.

As noted, Mardirossian discloses a system that utilizes sensors 7 to detect event related potentials indicative of a "brainprint." The "brainprint" is transmitted as wireless signals to a remote location where the "brainprint" is processed to determine what the individual intended to communicate. The determination of what the individual intended to communicate is not transmitted to another location where an expert (e.g., neurologist) is located for further review and analysis of the "brainprint."

Selvester does not cure the deficiencies of Mardirossian. Selvester does not teach or suggest establishing a communications link to an expert location; transmitting information concerning the interpretation to the expert location; and displaying a communication from the expert location on the display. The Examiner indicates that these elements are disclosed at col. 15, lines 1-9 and Fig. 3 of Selvester. Applicant disagrees.

Selvester discloses a computer that processes ECG data to arrive at an interpretation output signal, which is capable of driving a pictorial output display structure. Col. 6, lines 40-47. Based on the interpretation output signal, a visual presentation of a pictorial view of the heart can be displayed on a display. Col. 9, lines 53-62; col. 19, line 57-col. 20, line 57. The Examiner's reference to col. 15, lines 1-9 describes how the rules or scorecards are developed that are applied to the acquired ECG data for analyzing the acquired ECG data. The Examiner mischaracterizes the meaning of what is described in col. 15, lines 1-9. In addition, Fig. 3 does not show that interpreted data is transmitted to another location where an expert is located for further review of the acquired ECG data.

In addition, there is no suggestion or motivation to combine the teachings of Mardirossian and Selvester for at least the reasons discussed above with respect to Claim 1.

For these and other reasons, Mardirossian and Selvester do not teach or suggest the additional subject matter defined by Claim 2. Accordingly, Claim 2 is allowable. Claims 3 and 4 depend from Claim 2 and are therefore allowable for at least the reasons set forth above with respect to Claims 1 and 2.

With respect to independent Claim 10, Mardirossian does not teach or suggest among other things, a physiological data interpretation system comprising a physiological data acquisition device capable of acquiring physiological data and coupled to the library of physiological data records, the acquisition device having an interpretation module to generate an interpretation of the physiological data and a correlation module to compare the interpretation to the records in the library of physiological records and determine a set of correlated data records.

As noted, Mardirossian discloses a system that utilizes sensors 7 to detect event related potentials indicative of a "brainprint." The "brainprint" is transmitted to a remote location, where the signals 13 are processed.

The system of Mardirossian does not include an interpretation module that generates an interpretation of the "brainprint" until after the "brainprint" is compared to the preestablished patterns from the same individual.

Mardirossian also does not teach or suggest, among other things, a physiological data interpretation system comprising an output device coupled to the acquisition device as acknowledged by the Examiner. Office action dated May 6, 2004, page 5.

Selvester does not cure the deficiencies of Mardirossian. There is no suggestion or motivation to combine the teachings of Mardirossian and Selvester for at least the reasons discussed above with respect to Claim 1.

For at least the reasons noted above, Mardirossian and Selvester do not teach or suggest the subject matter of Claim 10. Accordingly, independent Claim 10 is allowable. Claims 11-24 depend from independent Claim 10, and are therefore allowable for at least the reasons set forth above with respect to Claim 10. In addition, the additional subject matter defined by dependent Claim 12 provides separate bases for allowance.

Claim 12 further specifies an expert location coupled to the acquisition device. Mardirossian does not teach or suggest an expert location coupled to the acquisition device.

As noted, Mardirossian discloses a system that utilizes sensors 7 to detect event related potentials indicative of a "brainprint." The "brainprint" is transmitted to a remote location where the "brainprint" is processed to determine what the individual intended to communicate. The determination of what the individual intended to communicate is not transmitted to another location where an expert (e.g., cardiologist) is located for further review and analysis of the "brainprint."

Selvester does not cure the deficiencies of Mardirossian. Selvester does not teach or suggest an expert location coupled to the acquisition device. As noted, Selvester discloses a computer that processes ECG data to provide a visual presentation of a pictorial view of the heart that can be displayed on a display. Col. 9, lines 53-62; col. 19, line 57-col. 20, line 57. The Examiner mischaracterizes the meaning of what is described in col. 15, lines 1-9. The Examiner's reference to col. 15, lines 1-9 describes how the rules or scorecards are developed that are applied to the acquired ECG data for analyzing the acquired ECG data. In addition, Fig. 3 does not show that interpreted data is transmitted to another location where an expert is located for further review of the acquired ECG data.

In addition, there is no suggestion or motivation to combine the teachings of Mardirossian and Selvester for at least the reasons discussed above with respect to Claim 10.

For these and other reasons, Mardirossian and Selvester do not teach or suggest the additional subject matter defined by Claim 12. Accordingly, Claim 12 is allowable. Claims 13-17 depend from Claim 12 and are therefore allowable for at least the reasons set forth above with respect to Claims 10 and 12.

With respect to independent Claim 25, Mardirossian does not teach or suggest, among other things, a method of interpreting physiological data including the act of interpreting the physiological data based on a predetermined set of criteria to generate an interpretation. As noted, Mardirossian discloses a system that utilizes sensors 7 to detect event related potentials indicative of a "brainprint." The "brainprint" is transmitted to a remote location and processed to determine what the individual was attempting to communicate. Col. 7, line 24-col. 8, line 57.

The system of Mardirossian does not interpret the "brainprint" based on a predetermined set of criteria to generate an interpretation. The meaning of an individual's "brainprint" is not determined until after the "brainprint" is compared to preestablished patterns from the same individual. As noted above, Applicant respectfully disagrees with the Examiner's

characterization of the Mardirossian reference for at least the reasons indicated above with respect to Claim 1.

Mardirossian also does not teach or suggest, among other things, a method of interpreting physiological data including the act of displaying the interpretation and the correlated physiological data records on a display as acknowledged by the Examiner. Office action dated May 6, 2004, page 7.

Selvester does not cure the deficiencies of Mardirossian. Selvester does not teach or suggest, among other things, a method of interpreting physiological data including the act of displaying the interpretation and the correlated physiological data records on a display. As noted above, Selvester discloses a computer that processes ECG data to provide a visual presentation of a pictorial view of the heart can be displayed on a display. Col. 9, lines 53-62; col. 19, line 57-col. 20, line 57. The visual presentation of the heart can include markers that represent one or more selected heart conditions based on the interpretation of the ECG data (see Fig. 6A). *Id.* The system of Selvester does not display the correlated physiological data records.

In addition, there is no suggestion or motivation to combine the teachings of Mardirossian and Selvester, for at least the reasons discussed above with respect to Claim 1.

For at least the reasons noted above, Mardirossian and Selvester do not teach or suggest the subject matter of Claim 25. Accordingly, independent Claim 25 is allowable. Claims 26-31 depend from independent Claim 25, and are therefore allowable for at least the reasons set forth above with respect to Claim 25. In addition, the additional subject matter defined by dependent Claim 27 provides separate bases for allowance.

With respect to Claim 27, Mardirossian does not teach or suggest establishing a communications link to an expert location; transmitting information concerning the interpretation to the expert location, transmitting information concerning the interpretation to the expert location, and displaying a communication from the expert location on the display. The Examiner indicates that these elements are disclosed at col. 2, lines 54-56 and col. 3, lines 47-49 of Mardirossian. Applicant disagrees.

As noted, Mardirossian discloses a system that utilizes sensors 7 to detect event related potentials indicative of a "brainprint." The "brainprint" is transmitted to a remote location where the "brainprint" is processed to determine what the individual intended to communicate. The determination of what the individual intended to communicate is not transmitted to another

location where an expert (e.g., neurologist) is located for further review and analysis of the “brainprint.”

Selvester does not cure the deficiencies of Mardirossian. Selvester does not teach or suggest establishing a communications link to an expert location; transmitting information concerning the interpretation to the expert location, transmitting information concerning the interpretation to the expert location, and displaying a communication from the expert location on the display. The Examiner indicates that this subject matter is disclosed at col. 15, lines 1-9 and Fig. 3 of Selvester. Applicant disagrees.

As noted, Selvester discloses a computer that processes ECG data to provide a visual presentation of a pictorial view of the heart can be displayed on a display. Col. 9, lines 53-62; col. 19, line 57-col. 20, line 57. The Examiner mischaracterizes the meaning of what is described in col. 15, lines 1-9. The Examiner’s reference to col. 15, lines 1-9 describes how the rules or scorecards are developed that are applied to the acquired ECG data for analyzing the acquired ECG data. In addition, Fig. 3 does not show that interpreted data is transmitted to another location where an expert is located for further review of the acquired ECG data.

In addition, there is no suggestion or motivation to combine the teachings of Mardirossian and Selvester for at least the reasons discussed above with respect to Claim 25.

For these and other reasons, Mardirossian and Selvester do not teach or suggest the additional subject matter defined by Claim 27. Accordingly, Claim 27 is allowable. Claims 28 and 29 depend from Claim 27 and are therefore allowable for at least the reasons set forth above with respect to Claims 25 and 27.

#### Claim Rejections – 35 U.S.C. § 103

Claim 7 is rejected under 35 U.S.C. § 103 as being unpatentable over Mardirossian in view of Selvester and further in view of U.S. Patent No. 6,139,494 (“Cairnes”).

Claim 7 depends from independent Claim 1 and is therefore allowable for at least the reasons set forth above with respect to Claim 1. In addition, there is no suggestion or motivation to combine Mardirossian, Selvester, and Cairnes. Cairnes discloses a clinical teleinformatics based system that provides outpatient health care delivery. The system includes a plurality of medical devices 100-106 that can be connected to a patient 108. Patient data can be acquired and transmitted to a personal health advisor 120 where the data is analyzed and recommended



treatment options generated. The patient 108 can access a medical library to obtain information about disease states, therapies and treatments, wellness and prevention, symptoms, and medical drugs.

There is no suggestion or motivation to combine Mardirossian and Selvester as set forth above with respect to Claim 1. There is also no suggestion or motivation to combine the system of Cairnes with the systems of Mardirossian and Selvester. The system in Cairnes is patient driven where the patient accesses a medical library. The systems in Mardirossian and Selvester are not accessed by the patient, but rather accessed by a physician or person trained in reading physiological data. In addition, the system in Mardirossian does not suggest a use for a library of education materials. The system in Mardirossian is only concerned with determining what the individual intended to communicate. There is no need to look up additional information and the "brainprint" is not used to interpret or diagnose a patient condition. Furthermore, the system in Selvester also does not suggest a need or a use for a library of education materials.

For these and other reasons, Mardirossian, Selvester, and Cairnes do not teach or suggest the additional subject matter defined by Claim 7. Accordingly, Claim 7 is allowable.

#### Claim Rejections – 35 U.S.C. § 103

Claim 18 is rejected under 35 U.S.C. § 103 as being unpatentable over Mardirossian in view of Selvester and further in view of U.S. Patent No. 6,203,495 ("Bardy").

Claim 18 depends from independent Claim 10 and is therefore allowable for at least the reasons set forth above with respect to Claim 10. In addition, there is no suggestion or motivation to combine Mardirossian, Selvester, and Bardy.

For these and other reasons, Mardirossian, Selvester, and Bardy do not teach or suggest the additional subject matter defined by Claim 18. Accordingly, Claim 18 is allowable.

#### Claim Rejections – 35 U.S.C. § 103

Claims 13 and 22 are rejected under 35 U.S.C. § 103 as being unpatentable over Mardirossian in view of Selvester and further in view of U.S. Patent No. 6,264,614 ("Albert").

Claim 13 depends from independent Claim 10 and is therefore allowable for at least the reasons set forth above with respect to Claim 10. In addition, there is no suggestion or motivation to combine Mardirossian, Selvester, and Albert.

For these and other reasons, Mardirossian, Selvester, and Albert do not teach or suggest the additional subject matter defined by Claim 13. Accordingly, Claim 13 is allowable.

Claim 22 depends from independent Claim 10 and is therefore allowable for at least the reasons set forth above with respect to Claim 10. In addition, there is no suggestion or motivation to combine Mardirossian, Selvester, and Albert.

For these and other reasons, Mardirossian, Selvester, and Albert do not teach or suggest the additional subject matter defined by Claim 22. Accordingly, Claim 22 is allowable.

#### Obviousness-Type Double Patenting Rejection

During the interview, the Examiner indicated that an obviousness-type double patenting rejection can be overcome by pointing out which claimed elements in the present application are not included in the claims of U.S. Patent No. 6,665,559 ("Rowlandson").

With respect to independent Claim 1 of the present application, Claims 1-17 of Rowlandson do not teach or suggest, among other things, a method of providing real-time decision support in the review of physiological data including the act of displaying the interpretation and the correlated physiological data records on a display.

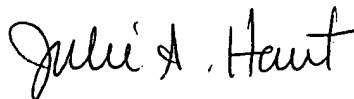
With respect to independent Claim 10 of the present application, Claims 1-17 of Rowlandson do not teach or suggest, among other things, a physiological data interpretation system including an output device coupled to the acquisition device to display the interpretation and the correlated physiological data records.

With respect to independent Claim 25 of the present application, Claims 1-17 of Rowlandson do not teach or suggest, among other things, a method of interpreting physiological data including the act of displaying the interpretation and the correlated physiological data records on a display.

**CONCLUSION**

In view of the above remarks, the Applicant respectfully requests entry of the amendment and allowance of Claims 1-31. The undersigned is available for telephone consultation at any time.

Respectfully submitted,

A handwritten signature in black ink, reading "Julie A. Haut". The signature is written in a cursive, flowing style.

Julie A. Haut  
Reg. No. 51,789

Docket No. 039199-9511-00  
Michael Best & Friedrich LLP  
100 East Wisconsin Avenue  
Milwaukee, Wisconsin 53202-4108  
(414) 271-6560